

**CLAIM SUMMARY**

Claim 1 (Previously canceled)

Claim 2 (Currently canceled)

Claim 3 (Previously canceled)

Claims 4-6 (Currently canceled)

Claims 7-8 (Previously canceled)

Claims 9-10 (Currently canceled)

Claim 11 (Previously canceled)

Claims 12-17 (Currently canceled)

Claim 18 (Previously canceled)

Claims 19-21 (Currently canceled)

Claims 22-23 (Previously canceled)

Claim 24 (Currently canceled)

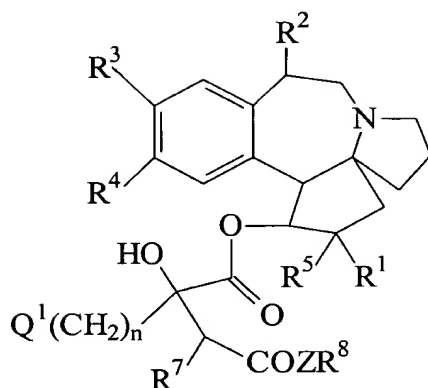
Claims 25-27 (Previously canceled)

Claims 28-30 (Currently canceled)

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Claim 31 (Re-presented-formerly claim 28) A method of treating leukemia

comprising administering to a human patient in need of such treatment using a  
subcutaneous mode of administration a harringtonine salt or tautomeric form thereof,  
wherein the harringtonine has the formula



wherein:

$R^1$  is H, OH, OMe, O-(C<sub>1</sub>-C<sub>30</sub>)-alkyl, O-aryl-(C<sub>1</sub>-C<sub>30</sub>)-alkyl, O-(C<sub>2</sub>-C<sub>30</sub>)-alkenyl, O-(C<sub>3</sub>-C<sub>30</sub>)-cycloalkyl or null and

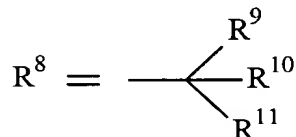
$R^2$  is H or OH, or  $R^1$ ,  $R^2$  form together -O-,

$R^3 = R^4 = \text{OMe}$  or  $R^3$  and  $R^4$  form together -OCH<sub>2</sub>O-,

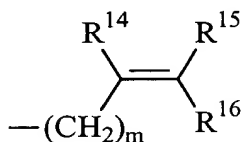
$n$  is 0 to 8,

$R^5$  is H, OH, OMe, O-(C<sub>1</sub>-C<sub>30</sub>)-alkyl, O-aryl-(C<sub>1</sub>-C<sub>30</sub>)-alkyl, O-(C<sub>2</sub>-C<sub>30</sub>)-alkenyl, O-(C<sub>3</sub>-C<sub>30</sub>)-cycloalkyl or O-aryl,

$Z = \text{O}, \text{S}, \text{or NH}$ , and



or  $Z-R^8$  is  $NR^{12}R^{13}$ ,  $R^{12}$  and  $R^{13}$  representing respectively  $R^9$  and  $R^{10}$ ,  
 $R^9$ ,  $R^{10}$ ,  $R^{11}$  are independently H,  $C_1-C_{30}$  alkyl,  $C_3-C_{30}$  cycloalkyl, aryl, aryl- $(C_1-C_{30})$ -alkyl,  $C_2-C_{30}$  alkenyl,  $C_2-C_{30}$  alkynyl,  $C_1-C_{30}$  trihalogenoalkyl,  $C_1-C_{30}$  alkylamino- $(C_1-C_{30})$ alkyl,  $C_1-C_{30}$  dialkylamino- $(C_1-C_{30})$ -alkyl, or amino- $(C_1-C_{30})$ -alkyl, or



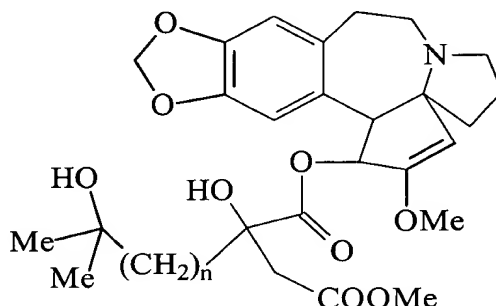
where  $R^{14}$ ,  $R^{15}$ ,  $R^{16}$  are independently H, halogen,  $C_1-C_{30}$  alkyl,  $C_3-C_{30}$  cycloalkyl, aryl, aryl- $(C_1-C_{30})$ -alkyl,  $C_2-C_{30}$  alkenyl or  $C_2-C_{30}$  alkynyl,  $C_1-C_{30}$  trihalogenoalkyl,  $m$  is 0 to 4,

each of these groups optionally including heteroatom(s),

wherein said harringtonine is in a formulation in which

- (i) the pH of the formulation is between 5.5 and 8.5,
- (ii) the harringtonines are in solution or hydrophilic freeze-dried powder ready-to-reconstitute of buffered salt of homoharringtonine or harringtonine, and
- (iii) the level of chromatographic purity of harringtonine is higher than 99.7%.

Claim 32 (New) The method of claim 31 where the harringtonine is homoharringtonine or harringtonine having the following formula



where  $n = 2$  or  $3$ .

Claim 33 (New) The method of claim 31 in which the acid which forms a salt of harringtonines is hydrochloric acid or tartaric acid.

Claim 34 (New) The method of claim 31 in which harringtonines are combined with another pharmaceutically acceptable agent in the same injection.

Claim 35 (New) The method of claim 34 in which the additional agent is a nucleoside.

Claim 36 (New) The method of therapy of claim 31 in which the subcutaneous mode of administration is performed by bolus injection at regular intervals.

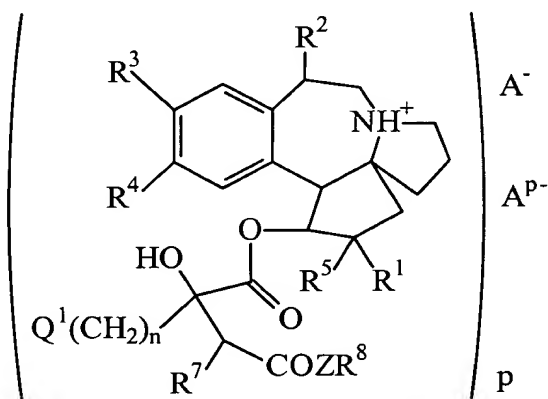
Claim 37 (New) The method of claim 31 in which the subcutaneous mode of administration is performed by continuous subcutaneous infusion.

Claim 38 (New) The method of claim 31, wherein at least one additional antitumor agent is administered with the harringtonine.

Claim 39 (New) The method of claim 31, wherein the leukemia is selected from the group consisting of chronic myeloid leukemia, acute myeloid leukemia, acute nonlymphocytic leukemia, acute romyelocytic leukemia and myelodysplastic syndrome.

Claim 40 (New) The method of claim 31, wherein chronic myeloid leukemia is the leukemia to be treated.

Claim 41 (New) The method of claim 31 where the harringtonine is a harringtonine salt having the following formula

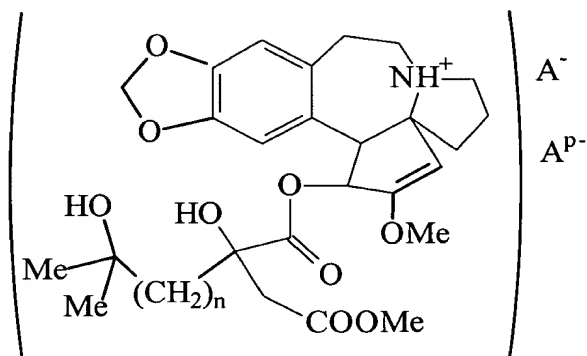


where  $A^-$  is

a mineral anion selected from the group consisting of chloride, sulfate, nitrate, and perchlorate, or

an organic ion selected from the group consisting of tartarate, malate, lactate, and citrate, and  $p$  is 1 or 2.

Claim 42 (New) The method of claim 31 where the harringtonine is a harringtonine salt having the following formula



where A<sup>-</sup> is

a mineral anion selected from the group consisting of chloride, sulfate, nitrate, and perchlorate, or

an organic ion selected from the group consisting of tartarate, malate, lactate, and citrate, and p is 1 or 2.

Claim 43 (New) The method of claim 35 in which the nucleoside is cytosine arabinoside.

Claim 44 (New) The method of claim 36 in which the subcutaneous mode of administration is performed by bolus injection at one to four injections a day for at least one day.

Claim 45 (New ) The method of claim 36, in which the subcutaneous mode of administration is performed by bolus injection at one to four injections a day for 28 days.